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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,745	03/05/2002	James H. Anderson	56,493 (71699)	8461
21874	7590	09/20/2007		
EDWARDS ANGELL PALMER & DODGE LLP			EXAMINER	
P.O. BOX 55874			SAADAT, CAMERON	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3714	
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			09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,745	ANDERSON ET AL.	
	Examiner	Art Unit	
	Cameron Saadat	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/28/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-54 and 57-66 is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to amendment filed 6/28/2007, claims 1-15 and 17-66 are pending in this application.

Claim 16 is cancelled.

Claim Objections

The claim objections of claims 51-54, 57, 59, and 61 set forth in the previous office action are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC §101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

Claims 29-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Independent claims 29 and 49 and their respective dependent claims are rejected under 35 U.S.C. 101 because the claims are directed to an abstract idea that is not tied to a physical transformation which would result in a practical application producing a tangible result to form the basis of statutory subject matter under 35 U.S.C. 101. A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. *See In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed Cir. 1994). In this case, the claimed rules are not tangible since the claims do not provide structure that would allow a user to appreciate and utilize the rules to aid in design of the medical device. In addition, with respect to claim 49, the claimed software suite should be tied to a computer-readable medium, in order to provide a physical transformation of the software to provide a tangible result.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-15, 17-20, 22-23, 25-26, 28 and 55-56 are rejected under 35 U.S.C. 102(b) as anticipated by Cai et al. - Parametrical Modeling Based Multi-Layered Approach for Design and Validation of Catheterization Devices (published June 1998); hereinafter Cai.

Regarding claim 1, Cai discloses a system for designing a medical device for accessing a body cavity or lumen of a patient comprising: providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a knowledge base, wherein the system performs an analysis using the provided data; and obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen. See p. 32-34. Cai also discloses a device shape knowledgebase comprising a plurality of geometries for at least one segment of a catheter; and rules for determining correspondence between a geometry of at least one segment and at least a portion of a model of the body cavity or lumen See p. 32-34.

Regarding claims 2, Cai discloses a device shape knowledge base comprising a plurality of geometries for at least one segment of a device and rules for determining correspondence between a geometry of at least one segment and at least a portion of the model of the body cavity or lumen. See p. 33, col. 2.

Regarding claim 3, Cai discloses a three-dimensional geometric model of the cavity or lumen is obtained from a volume image of the cavity or lumen. See p. 34, Col. 1.

Regarding claims 4, Cai discloses a volume image obtained from computer tomography scanning device. See id.

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Regarding claim 5, Cai discloses a knowledge base comprising data relating to a physical property of the cavity or lumen. The system includes data describing physical shape the patient's vasculature. See p. 33, Col. 2, ¶ 4.

Regarding claim 7, Cai discloses a recommendation from the knowledge base that is displayed on an interface of a user device connectable to a network. See p. 33, Col. 2, ¶ 2.

Regarding claim 9 Cai discloses selectable options corresponding to design parameters of the device are transmitted to, and displayed on, the interface of the user device from the knowledge base. See p. 35, Fig. 2.

Regarding claims 10, Cai discloses selectable options that are selected from the group consisting of: shape, material, flexibility, shape memory, stiffness, softness, pliability, stability, strength, contrast medium flow rate, length, size, and combinations thereof. See P. 32, Col. 2, ¶ 3.

Regarding claim 11, Cai discloses selectable options that are selected and the system simulates the design of the device based on the one or more selected options or parameters. See p. 33, Col. 2.

Regarding claim 12, Cai discloses a device selected from the group consisting of a catheter, a guidewire, a surgical device, a balloon, a balloon-inflating devices, a coils, a stents, stent-grafts, an endoscopes, a laparoscopes, a bronchoscopes, vascular occlusion devices, optical probes, and drug delivery device are equivalents known in the art for the same purpose of performing minimally invasive surgery. See p. 33, Col. 2.

Regarding claim 13, Cai discloses that the design of more than one device is simulated. See p. 33, Col. 2 – p. 34, Col. 1,

Regarding claim 14, Cai discloses that the parameters selected for one of the devices is based on parameters of at least one of the other devices. See p. 33, Col. 2 – p. 34, Col. 1,

Regarding claim 15, Cai discloses a medical device designed to access a lumen which is a blood vessel. See p. 32, Col. 2, ¶ 3.

Regarding claim 17, Cai discloses a device comprising multiple segments and parameters of one or more of the multiple segments are selected independently. See p. 33, Col. 2.

Regarding claim 18, Cai discloses a device selected from the group consisting of a catheter, a guidewire and a surgical device, a balloon, a balloon-inflating devices, a coils, a stents, stent-grafts, an endoscopes, a laparoscopes, a bronchoscopes, vascular occlusion devices, optical probes, and drug delivery device are equivalents known in the art for the same purpose of performing minimally invasive surgery. See p. 33, Col. 2.

Regarding claim 19, Cai discloses at least one segment selected from the group consisting of a tip, a rod element, a hook element and a hub. See p. 33, Col. 1, ¶ 3.

Regarding claim 20, Cai discloses two segments having varying material properties. See p. 33, Col. 1, ¶ 3.

Regarding claims 22, Cai discloses performing one or more feature operations to modify the recommended geometry. See p. 33, Col. 2.

Regarding claim 23, Cai discloses feature operations selected from the group consisting of shape sweeping, extruding, holing, braiding, edge rounding, and hub construction. See p. 33, Col. 1, ¶ 3.

Regarding claim 25, Cai discloses a knowledge base including clinical information relating to the patient. See p. 34, Col. 1.

Regarding claim 26, Cai discloses device geometry determined using Finite Element Analysis. See p. 34, Col. 1.

Regarding claim 28, Cai discloses a method wherein the patient has a pathology affecting the structure of the body cavity or lumen. See P. 33, col. 2, last ¶.

Regarding claims 55-56, Cai discloses a method further comprising: generating a geometric model of the body cavity or lumen from the provided data; and wherein said obtaining a recommendation from the system further includes obtaining a recommendation of a geometry, topology and physical

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properties of one or more devices for placement into the cavity or lumen using the generated geometric model. See p. 34, Col. 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of Anderson et al. - Virtual Reality in Interventional Radiology; Min Invas Ther & Allied Technol; 1997; Vol. 6 (hereinafter Anderson).

The surgical planning system disclosed by Cai does not describe modeling the physical property of elasticity of the cavity or lumen. Anderson discloses an analogous system in which deformations and distentions of blood vessels are modeled. See p. 115. In view of Anderson, it would have been obvious to an artisan to modify the surgical planning system disclosed by disclosed by Cai, to add the feature of modeling the physical property is the elasticity of the cavity or lumen. As suggested by Anderson, the modification would enhance the system by improving its performance in simulating procedures performed within a patient's venous system. See Anderson, p. 115.

Claims 8, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of DiGioia, III et al. U.S. 6,205,411 B1; hereinafter DiGioia.

Regarding claims 21, 24, and 43, Cai does not describe determining the best fit between the geometry of the device and the geometry of a path. DiGioia discloses an analogous surgical planning system which determines the best fit between a patient's anatomy and a custom-made tool for insertion into the patient. See col. 2:56-62; 4:66-5:11, 7:64-67. In view of DiGioia, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein

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the system assists surgeons in the design and selection of tools relative to a patient's vasculature, to add the feature of determining best fit between the geometry of the device and the geometry of a path. As taught by DiGioia, the modification would enhance the system by allowing the design of tools with the proper size and geometry for a particular patient's anatomy. See DiGioia, col. 2:56-62; 4:66-5:11, 7:64-67.

Regarding claim 8, Cai discloses all of the claimed subject matter with the exception of explicitly disclosing the feature of providing a recommendation in the form of a three-dimensional representation of the medical device. However, DiGioia discloses an analogous surgical planning system which See Figs. 5, 7a-e. In view of DiGioia, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein the system assists surgeons in the design and selection of tools relative to a patient's vasculature, to add the feature of presenting recommended medical devices in three-dimensional form, thereby determining best fit between the geometry of the device and the geometry of a path. As taught by DiGioia, the modification would enhance the system by allowing the design of tools with the proper size and geometry for a particular patient's anatomy. See DiGioia, col. 2:56-62; 4:66-5:11, 7:64-67.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cai in view of Ulug, U.S. 4,918,620.

Cai does not disclose displaying a rule used for making the recommendation in response to a query. Ulug discloses an expert system that displaying a rule used for making the recommendation in response to a query in order to allow a user to verify the veracity of the rule. See col. 3:3-51. In view of Ulug, it would have been obvious to an artisan at the time of the invention to modify the surgical planning system disclosed by Cai, wherein the system assists surgeons in the design and selection of tools, to add the feature of displaying a rule used for making the recommendation in response to a query. As taught by Ulug, the modification would enhance the system by allow a user to verify the veracity of a rule. See id.

Allowable Subject Matter

Claims 51-54 and 57-66 are allowed.

Response to Arguments

Applicant's arguments filed 1/28/2007 have been fully considered but they are not persuasive. Applicant emphasizes that Cai does not disclose a knowledge base, but instead discloses a database system wherein information is stored in the database and where needed specific data can be retrieved by the database. The examiner disagrees. Cai does not merely disclose a database, but additionally discloses a parametrical modeling technique wherein a recommendation is provided by optimizing parameter values (such as material properties, size, and shape, see p. 33, col. 1, last paragraph) based on given constraints (See P. 33, Col. 2). Applicant's definition of a knowledgebase is a data structure comprising facts and rules. See applicant's specification, p. 7, lines 6-9. Accordingly, Cai teaches a knowledge base by optimizing parameter values based on given constraints. However, it is additionally noted that claims are given their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH**

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shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is (571) 272-4443. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cameron Saadat
9/14/2007



Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3714